EXHIBIT 1

Forced-air warming discontinued: periprosthetic joint infection rates drop

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Abstract

Several studies have shown that the waste heat from forced-air warming (FAW) escapes near the floor and warms the contaminated air resident near the floor. The waste heat then forms into convection currents that rise up and contaminate the sterile field above the surgical table. It has been shown that a single airborne bacterium can cause a periprosthetic joint infection (PJI) following joint replacement surgery. We retrospectively compared PJI rates during a period of FAW to a period of air-free conductive fabric electric warming (CFW) at three hospitals. Surgical and antibiotic protocols were held constant. The pooled multicenter data showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW (n=2034; P=0.002). The 78% reduction in joint implant infections observed when FAW was discontinued suggests that there is a link between the waste FAW heat and PJIs.

Introduction

It is now generally recognized that in the absence of active warming, most surgical patients will become clinically hypothermic. It has also been shown that mild perioperative hypothermia is detrimental to a variety of outcomes including increased soft tissue infections (SSI),[1,2] increased bleeding and transfusion requirements,[3,4] increased risk of morbid cardiac events,[5] prolonged recovery and prolonged hospital stays.[1] As a result of these studies and others like them, FAW has become a Standard of Care for most surgical procedures.[6]

In 2009, we reported the results of our laboratory research showing that the waste air from FAW is not simply benign waste air, but is also approximately 1000 watts of waste heat (www.Heat-rises.blogspot.com). In some circumstances, the waste heat and air escapes from under the surgical drape near the floor, where it warms the contaminated air normally resident near the floor. The contaminated warm air forms into convection currents that rise along the sides of the surgical table, mobilizing the floor bacteria into the sterile surgical field above the patient. In other circumstances, the waste heat radiates through the surgical drape, inducing a tornado-like vortex near the anesthesia screen. This tornado-like vortex has been shown to vacuum contaminants from the floor and deposit them into the sterile surgical field.

The fact that waste FAW heat causes contamination of the sterile surgical field has been corroborated by seven peer-reviewed, published studies.[7-13] One study by Legg et al., for example, showed that there are 2000 times more contaminating particles above the surgical site when FAW is used than with air-free CFW.[7]

It has been shown that the concentration of contaminants in the air of the sterile surgical field correlates positively with the risk of PJI during total joint replacement surgery.[14-20] It is also known that in contrast to soft tissue SSIs, which require an inoculum of more than 1 million bacteria,[21] a single bacterium can cause a catastrophic PJI, and that the bacterium is usually an airborne contaminant.[16-18] Therefore, it is only logical to suspect that the contamination from the rising waste FAW heat could increase the risk of PJIs.

A large retrospective outcome study by McGovern et al, showed a correlation between the rising waste FAW heat and the majority of deep joint infections in total joint replacement surgery.[8] The investigators reported a 74% reduction in PJIs when they discontinued the use of FAW. The lower infection rates were achieved using air-free CFW warming: *[FAW] Patient warming ventilation disruption was associated with a significant increase in deep joint infections…*[8]

Similarly, airborne contamination has recently been linked to heart valve infections.[22] The FDA and the chain of infection (CDC) have both issued warnings about Nontuberculous *Mycobacterium* (NTM) infections associated with heater-cooler devices (HCD) used during cardiac surgery.[23,24] Heart valve infections were genetically linked to *Mycobacteria chimaera* growing in the water bath of the HCD machines, which are then aerosolized into the air of the operating room by the cooling fan of the HCD. The contamination and infections from both HCD and FAW share the following traits: biofilm-forming organisms are growing within the inaccessible parts of the devices that cannot be disinfected or cleaned (FAW also mobilizes skin bacteria shed from the surgical staff, which has settled to the floor); the organisms are aerosolized by high-velocity warm air blown into the operating room by the HCD and FAW equipment; the warm air forms into convection currents and rises as all warm air does; the rising convection currents of warm air easily penetrate the protective downward airflow of the ultraclean ventilation system; the airborne bacterium settles on the implanted foreign material (cardiac valve or hip/knee replacement) that is highly susceptible to infection; the bacterium protects itself in a biofilm coating and sprouts into an infection up to a year later.

FAW is a far worse offender than HCD: more waste heat (1000 watts), as much or more blowing air (40-50 cfm), and exhaustion of the waste heat and air inside the ventilation flow field. The McGovern study suggests that up to 74% of the 20,000 hip and knee implant infections that occur annually in the US may be caused by FAW. This is a very significant, but easily solvable, public health problem.

Materials and Methods

This study is designed to investigate periprosthetic joint infection (PJI) rates while using FAW (Bair Hugger®, 3M, St. Paul, MN, USA) compared with air-free CFW (HotDog®, Augustine Temperature

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Key words: Infection; Wound; Surgical site infection; Nosocomial infections; Health care associated infections.

Contributions: SDA gathered the data and wrote the paper.

Conflict of interest: SDA is the founder, CEO and holds equity in Augustine Temperature Management, LLC, the manufacturer of HotDog® CFW.

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Management, Eden Prairie, MN, USA). The measured outcome in each of these studies is PJI. This multicenter retrospective outcome study consists of data reported by three hospitals.

Each hospital report shares a study design similar to the McGovern study. In each study, a baseline PJI rate was determined for the FAW control group over a one-year period of time (t_{FAW}). FAW was then discontinued, and the hospital switched to air-free CFW warming. Any infections occurring during the first two months after the switch in warming technologies were disregarded. Given that PJIs do not necessarily occur in the immediate postoperative period, it would be impossible to know if an infection occurring during the *washout period* came from the FAW or CFW time period. Starting with month three of the CFW period, the PJI rate was determined for the following 6-24 months of data collection (t_{CFW}). The changes in PJI rates from t_{FAW} to t_{CFW} were then determined.

Only hospitals reporting that no other significant changes were made to their surgical and antibiotic prophylaxis protocols during the study period qualified to be part of this study. No effort was made to standardize surgical protocols, the assumption being that the averaging of the multicenter data would offset minor variations in protocols. No effort was made to control for demographic variables, with the assumption being that the average patient population using a given hospital for total joint replacement surgery does not change appreciably from year to year.

Model selection and parameter significance tests were performed by comparing differences in model deviance to the expectation value under the c^2 distribution (likelihood ratio test), 0.5 was added to each cell using Haldane correction for sparse observations. A paid, independent statistician performed statistical calculations.

Results

As shown in Table 1, each of the three hospitals reported in this study showed significant decreases in the PJI rates (81, 100 and 34%) when FAW was discontinued in orthopedic surgery. In each case, the lower PJI rate was achieved while using air-free CFW. The three hospitals reported in this study were the first three that the authors contacted. No other hospitals were omitted from the study for any reason.

Center #1 is a medium-sized independent regional healthcare network. Their PJI rate while using FAW was 1.55%, which decreased to 0.29% with CFW, a decrease of 81%. Center #2 is an independent orthopedic and sports institute. Their PJI rate while using FAW was 2.28%, which decreased to 0.0% with CFW, a decrease of 100%. Center #3 is a medium-sized community hospital. Their PJI rate while using FAW was 1.57%, which decreased to 1.03%

Table 1. Periprosthetic joint infection results.

Patient warming device	Developing infection, n (%)	Not developing infection,n (%)	Odds ratio (95% confidence interval)	P
Center #1				
Conductive fabric	2 (0.3)	675 (99.7)	1.0	0.029§
Forced air	6 (1.5)	382 (98.5)	4.59 (1.06, 19.85)	
Center #2				
Conductive fabric	0 (0.0)	218 (100)	1.0	0.031§
Forced air	4 (2.3)	171 (97.7)	11.47 (0.61, 214.43)	
Center #3				
Conductive fabric	2 (1.0)	192 (99.0)	1.0	0.70§
Forced air	6 (1.6)	376 (98.4)	1.33 (0.31, 5.78)	
Multicenter pooled results				
Conductive fabric	4 (0.4)	1085 (99.6)	1.0	0.002§
Forced air	16 (1.7)	929 (98.3)	4.28 (1.50, 12.19)	

Table 2. Chain of infection analysis.

Chain of infection methodology	HCD	FAW
1. Infectious agent	Biofilm producing *Mycobacterium chimaera*	Biofilm producing skin bacteria, especially *Staphylococcus*
2. Reservoir	The inaccessible internal water-flow pathway of the HCD	i) The inaccessible internal airflow pathway of the FAW blower; ii) the skin of the surgical staff
3. Portal of exit	Aerosolized into and exhausted with the heated cooling air	i) Aerosolized into and exhausted with the heated air; ii) skin cells and bacteria shed into the air of the OR from the surgical staff
4. Mode of transmission	i) Waste heat rises outside the ventilation flow field and is then entrained into the downward ventilation airflow; ii) The waste heat from the HCD is blown inside the ventilation flow field near floor. Much like the waste heat from FAW, it then rises	The waste FAW hot air escapes from under the lower edge of the surgical drape near the floor inside the ventilation flow field. It warms the contaminated air that is normally resident near the floor. The waste heat and the warmed contaminated floor air then rise alongside the surgical table and end up in the sterile surgical field above the patient
5. Portal of entry	Cardiac surgery	Orthopedic surgery
6. Susceptible host	The surgical patient receiving implanted foreign materials	The surgical patient receiving implanted foreign materials

HCD, heater-cooler device; FAW, forced-air warming.

with CFW, a decrease of 34%. The pooled multicenter data showed a PJI rate of 1.69%, which decreased 78 to 0.37% following the discontinuation of FAW and a switch to air-free CFW (n=2034; P=0.002).

Discussion

This is a multicenter observational outcome study investigating the possible relationship between FAW and PJI in hip and knee total joint replacement surgery. The data were collected retrospectively at three hospitals. The switch from FAW to air-free conductive fabric warming is the only independent variable identified during the study period. It is axiomatic that warming by convection is inefficient; resulting in the release of waste heat.[25] The most common brand of FAW was used by all three hospitals in this study. However, it must be noted that all other brands of FAW also release approximately the same amount of waste heat, thereby causing the same surgical contamination risks. The pooled multicenter data from the three hospitals reported in this study showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW. This pooled result corroborates the findings of the McGovern study, which reported a 74% decrease in PJI rates when FAW was discontinued and CFW was initiated.[8] Assuming that there were no other unreported significant changes in the surgical or antibiotic protocols during the study period, the significant drop in the PJI rates must be attributed to the discontinuation of FAW until proven otherwise.

The suggestion that FAW could simultaneously be causing PJIs and reducing soft tissue SSIs seems to be contradictory. However, this apparent contradiction is explained by the presence or absence of biofilm.[26] Biofilm is a coating of exopolysaccharide material that protects the bacterium from antibodies and antibiotics, effectively allowing it to hibernate for up to one year before sprouting into a full infection. Many bacteria can form biofilm coatings in the presence of implanted foreign materials, but cannot form effective biofilm in soft tissue.[26] The result is that the infectious process is fundamentally different in joint replacement surgery, where a single bacterium can cause an infection, compared to soft tissue surgery, where an inoculum of more than one million bacteria is usually required to cause an infection.[16-18] Patients receiving implants, especially orthopedic implants, are especially susceptible to infection because bacteria can form biofilm on the implant.

The often-referenced studies showing that FAW reduces SSIs were investigating soft tissue surgery (colon, breast and hernia), where effective biofilm cannot be formed.[1,2] With soft tissue surgery, maintaining normothermia by any means of active warming seems to lower the infection rate. Even heavily contaminated air cannot introduce the inoculum of more than one million bacteria into a wound, the quantity required for a soft tissue infection. In contrast, the results of this study suggest that FAW should not be used during joint replacement surgery, where a single bacterium is adequate to cause the PJI.[16-18]

There is a striking similarity between the waste heat and air from HCD causing heart valve infections and the waste heat and air from FAW causing PJIs after hip and knee replacement surgery. Using the CDC's *chain of infection* methodology, the similarities between HCD infections and FAW infections can be appreciated (Table 2).

The similarity between these infections and the equipment causing them supports the CDC's broad recommendation to not use any equipment that blows air in the operating room. *Nothing that blows air should be in an operating theater, if possible* and *...it is important not to blow air in the operating theater.*[24]

In summary, seven published studies have documented the contamination of the sterile surgical field by the rising waste FAW heat.[7-13] Now, there are two retrospective outcome studies investigating the linkage between the rising waste FAW heat and deep PJI in joint replacement surgery. Both of these studies show significant decreases in PJI rates when the use of FAW is discontinued. Discontinuing the use of FAW in this multicenter retrospective trial resulted in a reduction of the PJI rates of 78%, which is consistent with the 74% reduction reported by McGovern *et al*.[8] In both of these studies, the lower infection rates were achieved while using air-free CFW.

According to the American Academy of Orthopedic Surgeons, the incidence of periprosthetic joint infection after primary hip or knee arthroplasty is over 2% among the Medicare population.[29] Therefore, the approximately one million of these procedures performed annually in the US should result in 20,000 PJIs per year. 20,000 catastrophic, permanently disabling PJI infections per year would seem to qualify as a public health crisis if they have a common etiology. This study suggests that more than 15,000 of these infections (78%) may be caused by FAW and are thus preventable.

Given the current FAW contamination and infection research and the CDC's recent admonition against blowing air in the operating room, it may be that a randomized controlled trial (RCT) would be unethical at this point. Therefore, retrospective outcome studies are the most robust clinical information that is likely to be available on this topic, and additional studies should be encouraged.

Conclusions

Based on these data it seems prudent that hospitals and clinicians avoid using forced-air warming on patients during surgeries involving implanted materials, especially joint replacements, until it is proven to be safe.

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EXHIBIT 2

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,	)	MDL No. 15-2666 (JNE/FLN)
	)	VOLUME I
	)	PAGES 1-210

VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.

LOS ANGELES, CALIFORNIA

TUESDAY, JULY 11, 2017

Job No. 124786

DORIEN SAITO, CSR 12568, CLR

A Yeah. Up to -- up to the time of March 30.
Q Up to the time of March 30. You anticipated my next question.
Subsequent to March 30, have you reviewed any other materials that have in any way impacted your opinions in this matter?
A I've seen one additional peer reviewed publication by Augustine describing three -- interrupted time series studies of fecal infections in three institutions with a switch from forced-air warming to conductive warming.
Q Had you ever seen that publication before or the journal in which it was -- well, strike that.
You said it was a peer reviewed publication.
How did you determine that?
A My understanding was that it was a peer reviewed journal.
Q Where did that understanding come from?
A I guess acceptance that it was in the journal that I thought was peer reviewed.
Q Did you do anything to investigate whether it was a peer reviewed journal?
A Specifically, no.
Q Did you do anything to investigate whether it was --

Well, did you do anything to determine what -- whether the journal in which it was published was one that was widely read or -- or well respected in the -- in any particular medical fields?
A As I -- as I recall, the paper did have both a public -- sorry -- a submission and an acceptance date, which would imply to me that it was, in fact, peer reviewed.
I'm not specifically familiar with that journal versus other journals in the -- in that general area.
Q Have you -- you published hundreds of papers, haven't you?
A I've published hundreds of papers.
Q Have you ever had to pay to publish them?
A I'm sorry?
Q Have you ever had to pay to publish any of your publications?
A I would have to think because in today's online journal world, you sometimes pay. And whether some of my papers have to be in Class One [phonetic] or some of the journals where you pay. I'd have to look. That's something that's happening in today's publication world.
Q As you sit here today, can you remember

having yourself to pay an online publisher to publish a paper you had authored co-authored?
A I would have to look because I think some of our recent online papers had been in such journals regarding global health, but I -- I can't pull up the details of that today.
Q This Augustine publication that you -- that you read, how did you come to learn about its existence?
A I actually learned about it from, uh, Jan Conlin.
Q Okay. And how long ago did you read it?
A Oh, initially, within the last ten days probably.
Q Did you -- one of the things that you indicated that you reviewed prior to rendering your opinions in this matter was the -- hold on. I misspoke. I apologize. I withdraw that.
Have you ever read the deposition of Scott Augustine?
A Well, I -- I will say that I have seen a number of depositions. Would -- in all honestly, I have difficult saying this is the reliance list here in terms of what I looked at.
Q I -- I'm sorry. Could you explain that. So

Exhibit C is not a comprehensive --
A No. Exhibit C is what I looked at. I kind of --
Q Okay.
A Yeah.
Q And I assume you tried to be as comprehensive as possible.
A Yes. And reviewed the materials that I had in preparing this list.
Q I don't see the deposition of Scott Augustine included in the reliance materials.
Is that -- is that an oversight, or is that -- is that -- is it accurate that you did not read Dr. Augustine's deposition?
A Well, the -- the only thing I'm saying is that in preparing this list, we went through everything that was on hand in my office and had been sent to me. So unless we missed it, it's on here.
Q As you sit here today, do you have any independent recollection of having reviewed either the full Augustine transcript or any portions of his actual testimony?
A I -- I mean, again, I can't swear now having read through or at least skimmed through it. So many of these depositions. That one specifically.

Q Did you -- do you know if you had occasion to look at any of the exhibits that were marked at the Augustine deposition?
A I don't know.
Q Well, let me be more specific.
Do you recall when you saw this Augustine paper that you brought up that you said you saw maybe ten days ago, when you looked at it, did -- did you look -- did anything trigger a thought in your mind that "Gee, this looks like something I've already" -- "at least part of something that I've already seen before"?
A Not specifically, no.
Q That appeared to be like brand-new material?
A (Nodding head.) Yes.
Q So as you sit here today, do you have any information about the background of how that Augustine study came to be prepared, the underlying data, any -- any -- any information about it other than what was represented by Dr. Augustine in the publication itself?
A To my -- to my memory, my -- my understanding, that paper is based on reading it.
Q Has that paper had any impact on your opinions?

A I regard the paper as another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison.
Q You -- ultimately, your opinion in -- the -- the sort of the bottom line general opinion was that you concluded that the -- based on your epidemiological expertise, that the Bair Hugger -- use of the Bair Hugger in orthopedic surgery is a substantial contributing cause to the development of periprosthetic joint infection; is that right?
A That's the last sentence of my report, page 17.
Q I want to ask about this phrase "substantial contributing cause."
Is that a concept that's used in the field of epidemiology?
A Well, I think there are a number of different approaches taken to describe causation, strength of causation, contribution to cause. There's -- so I -- it's -- it's a word that I have seen used or a phrase that I've seen.
Q It's not a phrase that you use, though; right?
A I think it would depend on the context.

If -- this refers to the magnitude of excess risk. So it's a description based on the odds ratio of the strength of association.
Q You've written or co-authored hundreds of -- of papers and studies that looked at odds ratios, attributable risk, and things like that, and drawn causal conclusions; right?
A In -- in -- in various activities and not specifically in the context of my papers. I've worked on reports and other expert documents that had causal conditions.
Q Would it surprise you that not one of your publications has ever used the phrase "substantial contributing cause"?
A I -- I'm not sure what the basis for your statement is, but...
Q Would you -- would it surprise you that if you were to search everything that you've written, that the phrase "substantial contributing cause," that exact phrase, never appears in anything that you've authored or co-authored?
A I really don't -- don't -- just don't have an opinion.
Q Well, wouldn't you agree that -- that the notion of something being a substantial contributing

cause is not something that -- that you, at least in your professional activities as an epidemiologist, have looked at or -- or used as a reference point?
MS. CONLIN: Objection as to form --
THE WITNESS: Well --
MS. CONLIN: -- it mischaracterizes his testimony.
THE WITNESS: Well, again, I think in terms of the question of causation, there are two -- two issues.
One is, Does an agent cause whatever the outcome is that's being considered?
And the second is, What's the magnitude of its contribution to causation?
So certainly I've written about both aspects of causation; the question of Is an agent causal? And then second, What is its contribution?
BY MR. GORDON:
Q Well, what constitutes a substantial contributing cause as opposed to a contributing cause that isn't substantial?
A Well, you know, again, I don't have strict numerical criteria.
But here I think the basis for the

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about the surveillance time in Wansbeck, I thought it started in October '08. I just -- which is why I had wondered with that -- somewhere in 2008 with the lower rates earlier in the year.

But in any case, I mean, yes, there's some variation in this moving average.

Q And from a statistical standpoint, you're -- you think that the proper way to analyze these data is to just say "Well, we'll just" -- "we're just going to compare the overall average of a twenty-month period that goes up and down and up to a seven-month period"?

A No. Let me say --

MS. CONLIN: Well, objection -- objection as to form in terms of the time.

THE WITNESS: Sorry. Forgive me. Just restate the question for me.

MR. GORDON: Well, I don't think it was accurate. So, Jan, if you want to enlighten me as to where I -- I misspoke I would be happy to --

MS. CONLIN: Well, I --

MR. GORDON: -- be educated.

MS. CONLIN: -- I can't tell from -- I don't want to have a speaking objection, but I think --

MR. GORDON: I'm inviting you.

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MS. CONLIN: All right. The -- this chart starts on September 1st, 2007, which we think the record is pretty clear. And it's an inaccurate -- inaccurate data set for that. So that -- that was the issue, but I didn't want to --

MR. GORDON: Okay. No. I'm glad you -- and that's fine. Let's -- I will clarify -- clarify my question then. I wasn't -- that wasn't what I was intending to ask.

Q I'm talking about the twenty-month period that is depicted in Professor Holford's Figure 2 as the Bair Hugger study period. There's a red line across that corresponds to the study time period reflected in the McGovern paper. And that's a seven-month period that is identified here as the HotDog study. Those are -- are the two periods I was referring to.

And you've got twenty months of -- of data in the Bair Hugger study that go to a low, as you say, of, it looks like, less than 1 percent to a high of 4 or 5 percent during that twenty months. And then you've got -- and that's being compared to the average of seven months of data from McGovern -- or from the HotDog period.

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Do you think from an epidemiological standpoint that averaging data with that kind of variability over twenty months and comparing it to a seven-month period is sound epidemiological methodology?

A Well, yeah, let me comment from a different perspective. I've done a lot of time series analyses.

This data set is simply too small to do any sort of formal analysis. It's small. It's -- I'll use the word "noisy." And probably the best way to get a stable signal is to average the data that is at hand.

Q When you have a small and noisy series, doesn't that impact the -- the weight that you can give to any conclusions from it?

A Well, again, as I said, the best way to try to understand what the signal is, is to average all the data you have and -- and use it all.

Q You're saying the best way under adverse -- the -- the less than ideal circumstances of having a small and noisy data set?

A I'm simply referring to the data at hand in this -- in this picture.

Q In your professional work, either your teaching or if you do health organization bodies like

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that, would you recommend a change in practice based upon a single observational study that has this limited data set and is this noisy?

MS. CONLIN: Objection as to form, it misstates his report.

THE WITNESS: Yeah. Again, my conclusions as I've -- the conclusion of my report is not based solely on the McGovern data set. There's extensive review of other materials.

BY MR. GORDON:

Q Yeah, and we're going to -- and I -- and I am confining my questions to McGovern.

So if -- if you take had the McGovern paper out of your consideration, are you saying that your -- your opinion would remain the same, that the Bair Hugger is a substantial cause of surgical site infections, substantial to -- or to periprosthetic infections?

MS. CONLIN: It calls for speculation.

THE WITNESS: I -- I -- the only comment I could make is that there's now a second study, the Augustine report, with another -- an est- -- another estimate of the risks of this too. That's I think what I can say at this point.

///

EXHIBIT 3

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- -

DEPOSITION OF JONATHAN BORAK

VOLUME I, PAGES 1 - XXX

JULY 20, 2017

(The following is the deposition of JONATHAN BORAK, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 8:00 o'clock a.m., July 20, 2017.)

14:02:43 associated with the use of the Bair Hugger."
14:02:45 A. I did say that.
14:02:46 Q. Okay. And there --
14:02:49 Since that time there's been the Augustine
14:02:51 paper that's been published; correct?
14:02:53 A. Correct.
14:02:53 Q. And I take it that doesn't change your
14:02:55 views.
14:02:55 A. No. I think little of the Augustine paper.
14:02:59 Q. You think little of the Augustine --
14:03:01 Why is that?
14:03:02 A. It doesn't seem to follow its protocol, it
14:03:06 seems to have cherry picked data.
14:03:09 Q. What kind of cherry picking?
14:03:11 A. Hmm. There are data from Ridgeview Medical
14:03:16 Center that were apparently provided under whatever
14:03:19 process legally which shows a compilation of knee and
14:03:24 hip surgeries and infectious rates for four years,
14:03:31 2006, 2007, 2008, 2009. Looking at the recent
14:03:39 Augustine paper, it appears that he only dealt with
14:03:44 the knees, not the hips, nor the two combined, that he
14:03:50 compared 2006 knees to 2008 and 2009 knees, which was
14:04:00 not at all what he said would be the protocol, which
14:04:03 was a two-month or three-month washout period, and
14:04:08 that he selectively -- selectively excluded the 2007

14:04:13 data. And so it doesn't look to me as though the
14:04:15 Augustine paper is based upon legitimate data, it
14:04:19 looks as though -- well "legitimate," real but
14:04:23 selected in a way to influence the appearance of an
14:04:25 outcome.
14:04:26 Q. How about the other two centers?
14:04:27 A. I don't have any data on them.
14:04:30 Q. Now in paragraph 24 --
14:04:32 Oh, by the way, is there anything else that
14:04:34 you want to say about why you think very little of the
14:04:38 Augustine paper?
14:04:40 A. Well it's clear that he doesn't provide
14:04:42 enough information about the cases, and his statement
14:04:48 which is that nothing else changed is contradicted by
14:04:55 statements from that Ridgeview Medical Center itself,
14:04:59 so my sense of it is that the data are not what he
14:05:04 presents or that he misrepresents the data, and that
14:05:08 he excluded a year's worth of data which would not
14:05:12 have enhanced the comparison, that he deviated from
14:05:16 the protocol, and that he excluded the hip data.
14:05:21 Q. Excluded the hip? I'm sorry.
14:05:23 A. Excluded the hip data --
14:05:24 Q. Oh hip. Okay. Yeah.
14:05:26 A. -- and did not present the paper properly.
14:05:29 He says that he did a replica or something -- I'm

EXHIBIT 4

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- -

DEPOSITION OF THEODORE R. HOLFORD

VOLUME I, PAGES 1 - XXX

JULY 18, 2017

(The following is the deposition of THEODORE R. HOLFORD, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulebard, Hartford, Connecticut, commencing at approximately 9:00 o'clock a.m., July 18, 2017.)

16:46:01 certainly give you more power.
16:46:02 Q. Yeah. It would -- it would be a more
16:46:04 accurate representation of whether those two variables
16:46:06 were confounders or not; correct?
16:46:09 A. If that's what you were interested in.
16:46:10 Q. Okay. It would be a more accurate
16:46:13 representation as to whether there in fact is an
16:46:17 increased odds ratio; correct?
16:46:19 A. For -- for --
16:46:21 Q. The use of the device and the outcome of
16:46:23 infection.
16:46:24 A. The use of the device, it would give a
16:46:26 better estimate of that, yes.
16:46:27 Q. Okay. The recent Augustine study does that;
16:46:30 correct?
16:46:30 A. The --
16:46:32 This is the published -- the one that was
16:46:34 just published?
16:46:35 Q. Yeah.
16:46:36 A. Well I mean the recent study has its own --
16:46:41 has a -- has the potential for bias that is also in
16:46:48 McGovern.
16:46:48 Q. Okay. But my question is different. The
16:46:51 recent Augustine article has a larger patient
16:46:54 population; --

16:46:54 A. It's a larger patient population. It is a
16:46:58 larger patient population. I think it is, yes.
16:46:58 Q. And the article notes that there was no
change in the thromboprophylaxis or the antibiotic
16:47:05 regimen; correct?
16:47:05 MR. GORDON: Object to the form of the
16:47:06 question, assumes facts -- mis -- it completely
16:47:08 misstates the evidence.
16:47:11 A. I -- the -- the --
16:47:13 The paper says very little about -- very --
16:47:19 very little detail about -- about -- about the
16:47:21 population. I think it says that, yes.
16:47:23 Q. Okay. So we've established that it's a
16:47:25 larger population and that the study does say that
16:47:28 there was not a change in the thromboprophylaxis or
16:47:31 antibiotic; is that correct?
16:47:32 MR. GORDON: Counsel, it doesn't say that.
16:47:34 Let him read it if you're going to -- you know, make
16:47:36 it up -- make up stuff.
16;47:39 THE WITNESS: Where specifically does it say
16:47:41 that?
16:47:42 MR. SACCHET: Okay.
16:47:56 (Exhibit 28 was marked for
16:47:58 identification.)
16:47:58 BY MR. SACCHET:

16:47:59 Q. Is this a copy of the recent Augustine
16:48:02 publication in Orthopedic Reviews?
16:48:04 A. Yes, it is.
16:48:04 Q. Okay. We can see that on page one there is
16:48:09 a subject header entitled "Materials and Methods;"
16:48:11 correct?
16:48:11 A. Yes.
16:48:14 Q. In the bottom right-hand corner.
16:48:15 And it says, "This study is designed to
16:48:19 investigate periprosthetic joint infection (PJI) rates
16:48:22 while using FAW (Bair Hugger, 3M, St. Paul, Minnesota,
16:48:25 USA) compared with air-free CFU (HotDog, Augustine
16:48:31 Temperature Management, Eden Prairie, USA);" correct?
16:48:33 A. Yes.
16:48:34 Q. The next paragraph says, "Each hospital
16:48:37 report shares a study design similar to the McGovern
16:48:37 study;" correct?
16:48:38 A. Yes.
16:48:39 Q. "In each study, a baseline PJI rate was
16:48:42 determined for the FAW control group over a one-year
16:48:45 period of time. FAW was then discontinued, and the
16:48:48 hospital switched to air-free CFW warming;" correct?
16:48:52 A. Yes.
16:48:53 Q. Okay. The top of the next column says,
16:48:55 "Only hospitals reporting that no other significant

16:48:59 changes were made to their surgical and antibiotic
16:49:01 prophylaxis protocols during the study period
16:49:04 qualified to be part of this study." Do you see that?
16:49:07 A. Yes.
16:49:11 Q. It says that there were no changes to
16:49:13 antibiotic prophylaxis protocols; correct?
16:49:15 A. That's what it says, yes.
16:49:17 Q. Do you have any reason to doubt that?
16:49:21 A. I've --
16:49:22 I don't know. I mean that's what -- that's
16:49:24 what it says. I don't -- it -- it --
16:49:27 I mean we have very little detail here
16:49:29 about -- about any variables other than -- other than
16:49:36 the device that was used, --
16:49:37 Q. Okay. Do you have any --
16:49:39 A. -- so -- on the patients or --
16:49:42 I mean there's no table here giving basic
16:49:50 demographics about the -- about the patient
16:49:53 population.
16:49:54 Q. Demographics are different than whether
16:49:56 there were changes to the surgical and antibiotic
16:49:58 prophylaxis protocols; correct?
16:50:00 A. They are diff -- they are, but I mean all --
16:50:04 all I'm -- all I'm indicating is that details --
16:50:06 Q. Okay.

16:50:06 A. -- related to what was done in this study
16:50:08 are pretty skimpy.
16:50:10 Q. Have you tried to investigate the details
16:50:12 that you would otherwise like to know?
16:50:13 A. Oh. I mean you can look at any other paper.
16:50:17 I mean there's lots of reports on the -- on the -- on
16:50:20 the characteristics of the patients, what's the age
16:50:23 distribution of the patients that they're looking
16:50:25 at, --
16:50:25 Q. Have you contacted --
16:50:26 A. -- how many males, how many females were, --
16:50:29 Q. Okay.
16:50:29 A. -- what is the racial distribution of -- of
16:50:30 the paper. I mean there's a -- the --
16:50:32 The list of things that are not here --
16:50:35 Q. Okay.
16:50:36 A. -- is pretty remarkable.
16:50:37 Q. What is here? There's a statement that says
16:50:40 only hospitals reporting that no other significant
16:50:42 changes were made to their surgical and antibiotic
16:50:45 prophylaxis protocols during the study period
16:50:48 qualified to be part of this study.
16:50:49 A. Okay.
16:50:50 Q. Do you have any basis, scientific or
16:50:52 otherwise, to doubt the veracity of that statement?

16:50:55 A. No.
16:50:55 Q. If we look at Table 1, there are three
16:50:59 centers denominated in the table; correct?
16:51:02 A. That's correct.
16:51:03 Q. And the first center has broken down between
16:51:09 conductive fabric and forced air; correct?
16:51:12 A. Yes.
16:51:12 Q. And the odds ratio based on the increase in
16:51:14 infection from the use of forced air instead of
16:51:17 conductive fabric is 4.59 as reported in this study,
16:51:21 correct?
16:51:21 A. That's what they report, yeah.
16:51:22 Q. Okay. That's the question.
16:51:24 The second center also evaluates the change
16:51:27 from conductive fabric to forced air and it finds an
16:51:30 odds ratio of 11.47 as reported in Table 1; correct?
16:51:34 A. That's what they report.
16:51:36 Q. Both of those odds ratios are higher than
16:51:38 what was reported in the McGovern study; correct?
16:51:41 A. That's true.
16:51:42 Q. The second odds ratio of 11.47 is almost
16:51:49 three times the size of what was reported in the
16:51:52 McGovern study; correct?
16:51:55 A. That's the -- the -- you're --
16:51:58 You're referring to just the point estimate.

16:51:59 Q. Just the odds ratio.
16:52:00 A. Just the point estimate.
16:52:02 Q. Yeah, that's the question.
16:52:03 A. It is large, yes.
16:52:04 Q. Okay. And the center three, in all
16:52:09 fairness, reported a 1.33 odds ratio; correct?
16:52:11 A. That's right.
16:52:12 Q. The multi-center pool results based on those
16:52:15 three institutions totaling a population of over 2,000
16:52:20 persons --
16:52:21 Correct?
16:52:22 A. Yes.
16:52:23 Q. -- found a collective odds ratio of 4.28;
16:52:27 correct?
16:52:27 A. That's right.
16:52:27 Q. That is higher than what's reported in the
16:52:29 McGovern study; correct?
16:52:30 A. That point estimate is higher.
16:52:31 Q. It's doubled in the size of the odds ratio
16:52:34 of 2.16 that you reported in your study.
16:52:37 A. It's twice -- twice that, yes.
16:52:39 Q. It's four times the size of the odds ratio
16:52:42 that you reported when controlling for both the
16:52:44 thromboprophylaxis and the antibiotic; correct?
16:52:46 A. That's correct.

16:52:47 Q. The population is four times the size.
16:52:51 A. That's --
16:52:53 Is it four times?
16:52:55 Q. Your population was approximately 600
16:52:57 persons.
16:52:57 A. Oh, I see. You're talking about --
16:53:00 That's true, yeah.
16:53:01 Q. Okay. Based on this size of the
16:53:03 population -- well strike that.
16:53:08 The p-value for the multi-center pool result
16:53:11 is .002; correct?
16:53:13 A. That's right.
16:53:14 Q. That is a statistically significant p-value;
16:53:18 correct?
16:53:18 A. That is. The -- the confidence interval is
16:53:26 still 10.
16:53:27 Q. It's half the size of the confidence
16:53:29 interval you reported in the Jensen re-analysis;
16:53:33 correct?
16:53:33 A. The --
16:53:34 For that particular association, yes. But
16:53:37 it's not that different from the confidence interval
16:53:40 that was reported in McGovern.
16:53:43 Q. Okay. If we could --
16:53:53 A. May I --

16:53:54 There are other aspects of this -- of this
16:53:57 this --
16:53:57 Q. I haven't asked about them, so perhaps --
16:54:00 A. I know you haven't asked about it.
16:54:02 Q. Perhaps you can explain them when Mr.
16:54:04 Gordon --
16:54:04 A. Okay.
16:54:06 Q. -- asks you some questions.
16:54:07 With respect to the conclusions that you
16:54:08 offer in the epi section of your report --
16:54:14 MR. GORDON: What section?
16:54:15 Q. -- the epidemiology section of your report
16:54:17 regarding drawing causal inferences, there is that
16:54:20 part of your report; right?
16:54:20 A. Yes.
16:54:21 Q. Okay.
16:54:36 MR. GORDON: Are you talking about
16:54:37 "Causation findings," that section?
16:54:39 THE WITNESS: Yeah, that's what he's
16:54:40 referring to.
16:54:41 MR. SACCHET: Yeah. That was inartful.
16:54:43 Q. The first factor that you analyzed was the
16:54:46 temporality --
16:54:47 A. Yeah.
16:54:48 Q. -- of -- of -- of this data. You agree that

EXHIBIT 5

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- -

DEPOSITION OF THEODORE R. HOLFORD

VOLUME I, PAGES 1 - XXX

JULY 18, 2017

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16:50:52 otherwise, to doubt the veracity of that statement?

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16:50:59 centers denominated in the table; correct?
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16:51:17 conductive fabric is 4.59 as reported in this study,
16:51:21 correct?
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16:52:34 of 2.16 that you reported in your study.
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16:52:39 Q. It's four times the size of the odds ratio
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16:52:44 thromboprophylaxis and the antibiotic; correct?
16:52:46 A. That's correct.

16:52:47 Q. The population is four times the size.
16:52:51 A. That's --
16:52:53 Is it four times?
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16:53:27 Q. It's half the size of the confidence
16:53:29 interval you reported in the Jensen re-analysis;
16:53:33 correct?
16:53:33 A. The --
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16:53:40 that was reported in McGovern.
16:53:43 Q. Okay. If we could --
16:53:53 A. May I --

16:53:54 There are other aspects of this -- of this
16:53:57 this --
16:53:57 Q. I haven't asked about them, so perhaps --
16:54:00 A. I know you haven't asked about it.
16:54:02 Q. Perhaps you can explain them when Mr.
16:54:04 Gordon --
16:54:04 A. Okay.
16:54:06 Q. -- asks you some questions.
16:54:07 With respect to the conclusions that you
16:54:08 offer in the epi section of your report --
16:54:14 MR. GORDON: What section?
16:54:15 Q. -- the epidemiology section of your report
16:54:17 regarding drawing causal inferences, there is that
16:54:20 part of your report; right?
16:54:20 A. Yes.
16:54:21 Q. Okay.
16:54:36 MR. GORDON: Are you talking about
16:54:37 "Causation findings," that section?
16:54:39 THE WITNESS: Yeah, that's what he's
16:54:40 referring to.
16:54:41 MR. SACCHET: Yeah. That was inartful.
16:54:43 Q. The first factor that you analyzed was the
16:54:46 temporality --
16:54:47 A. Yeah.
16:54:48 Q. -- of -- of -- of this data. You agree that